

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Biomedical Device Consultants &
Laboratories of Colorado, LLC,

Civil File No. _____

Plaintiff,

**COMPLAINT FOR PATENT
INFRINGEMENT**

vs.

TA Instruments - Waters LLC,

Defendant.

Plaintiff, Biomedical Device Consultants & Laboratories of Colorado, LLC
("BDC"), hereby states for its Complaint against TA Instruments – Waters LLC
("Defendant") as follows:

NATURE OF ACTION

1. BDC is the owner by assignment of United States Patent Nos. 8,584,538 (the "'538 Patent," a copy of which is attached hereto as Exhibit A), 8,627,708 (the "'708 Patent," a copy of which is attached hereto as Exhibit B), 9,186,224 (the "'224 Patent," a copy of which is attached hereto as Exhibit C), and 9,237,935 (the "'935 Patent," a copy of which is attached hereto as Exhibit D), (collectively, the "Patents-In-Suit"). As set forth more fully below, Defendant has infringed each of the Patents-In-Suit without authorization by BDC.

THE PARTIES

2. BDC is a Colorado limited liability company with a principal place of business in Wheat Ridge, Colorado.

3. Defendant is a Delaware limited liability company, and upon information and belief, with a principal place of business in New Castle, Delaware.

4. BDC and Defendant are direct competitors in the field of medical device testing equipment.

5. Defendant and its parent and affiliated entities are listed as assignees of at least 50 patents and patent applications, many (if not all) of which are directed to medical device testing. Some or all of the Patents-In-Suit have been cited in the prosecution of their patent applications. For example, the '538 Patent and '708 Patent were cited in the prosecution of Application No. 14/306,508, which the U.S. Patent and Trademark Office's records indicate is assigned to Defendant.

JURISDICTION AND VENUE

6. This is an action for patent infringement arising under the Patent Laws of the United States. This Court has original jurisdiction over this patent infringement action under 28 U.S.C. §§ 1331 and 1338(a).

7. The Court has personal jurisdiction over Defendant.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1400(b). Upon information and belief, Defendant maintains a regular and established place of business in Minnesota through its permanent office in Eden Prairie, MN, which Defendant calls "TA Electroforce." Upon information and belief, Defendant manufactures, performs its own testing of, and services products that infringe the Patents-In-Suit at its TA Electroforce facility.

THE PATENTS-IN-SUIT

9. BDC is the owner of the Patents-in-Suit as original assignee, with full rights to pursue recovery of royalties or damages, including full rights to recover past and future damages, and injunctive relief for infringement of such patents.

10. BDC has complied with the requirements of 35 U.S.C. § 287 with respect to each of the Patents-In-Suit.

11. Generally, the Patents-in-Suit disclose a device for testing heart valves at a high rate of speed. That device includes, for example, a test chamber, a signal generator that outputs a waveform, and a fluid displacement member connected with and drive by a drive motor to displace fluid in the test chamber. Additionally, the Patents-in-Suit generally claim a method for testing heart valves at a high rate of speed that includes, for example, generating a waveform, reciprocally moving a fluid displacement member connected to and driven by a driving motor to provide a pressure source, and controlling the rate of differential pressure change across the tested heart valve.

DEFENDANT'S INFRINGING PRODUCTS

12. Defendant makes, sells, and offers to sell the ElectroForce line of cardiovascular test products. *See generally* Exhibit E (“ElectroForce® Cardiovascular Test Instruments” brochure). Among the features that Defendant touts in the ElectroForce product line are the products’ “[u]nmatched waveform control” and “precise control of displacements, forces, and pressures.” *See id.* at 11; *see also id.* at 16, 18, 24, 30. Defendant also touts the use of a “flexible control system,” with “[p]owerful

waveform generation tools to quickly create periodic waveforms for fatigue tests and block grouping to create more complex tests.” *See id.* at 30.

13. The ElectroForce line includes products for performing accelerated wear testing of heart valve devices, including the DuraPulse Heart Valve Test (“DuraPulse”). *See id.* at 9. The DuraPulse tests heart valve devices at a frequency of 15 to over 30 Hz, well beyond the normal human physiological rate and exceeding 200 BPM, and with differential pressure ranging up to 500 mmHg. *See id.* at 24. The DuraPulse includes application software to define and display testing conditions, including the target pressure, peak pressure duration, pressure across the valve device, and the number of test cycles. *See id.* at 31.

14. Defendant has been advertising the DuraPulse since at least December 2015. *See* http://www.tainstruments.com/wp-content/uploads/ESG_12-2015-1.pdf.

15. Defendant distributes promotional and other materials directed to using the DuraPulse to perform fatigue testing of heart valve devices. *See, e.g.*, Exhibit F (“ElectroForce® Heart Valve Testing Solutions DuraPulse™” brochure); <https://www.youtube.com/watch?v=KgmpQCRrYpQ&feature=youtu.be>.

16. BDC has notified both Defendant and its predecessor which made the DuraPulse of the Patents-In-Suit and the infringement by the DuraPulse. In July 2014, BDC sent a letter to the ElectroForce Systems division of Bose Corp. expressing concern that the DuraPulse infringed, attaching copies of the ’538 Patent, the ’708 Patent, and the published patent application that later issued as the ’935 Patent. Upon information and belief, in 2015, Defendant acquired the ElectroForce Systems division of Bose Corp. On

February 23, 2016, BDC wrote to Defendant, reiterating concern of infringement by the DuraPulse and providing the patent numbers of the Patents-In-Suit. In subsequent correspondence, Defendant indicated that it analyzed the patents and, it appears, found that the DuraPulse infringed all of the Patents-In-Suit.

**FIRST CAUSE OF ACTION
DIRECT INFRINGEMENT OF THE '538 PATENT**

17. BDC incorporates by reference each of the allegations in paragraphs 1-16 above.

18. On November 19, 2013, the '538 Patent, entitled a "Fatigue Testing System for Prosthetic Devices," was duly and legally issued by the United States Patent and Trademark Office.

19. Each claim of the '538 Patent is valid and enforceable.

20. Since at least December 2015, Defendant has directly infringed at least one claim of the '538 Patent and, unless enjoined, will continue to do so, by making, using (*e.g.*, through its own testing), offering for sale, selling and/or importing into the United States infringing products without authorization from BDC.

21. For example, and without limitation, the DuraPulse meets every limitation of at least independent claims 1 and 6 and dependent claims 2-5, 7-9, and 14 of the '538 Patent, either literally or under the doctrine of equivalents. Additionally, Defendant's use of the DuraPulse performs every step of at least independent claim 10 and dependent claims 11-13 of the '538 Patent, either literally or under the doctrine of equivalents.

22. The DuraPulse is a system for performing accelerated testing of valved prosthetic devices. *See* Exhibit F at 1-4. It has a test chamber. *See id.* at 2-3. It generates a non-regular waveform used to test a prosthetic heart valve. *See id.* at 4. It has a drive motor and a fluid displacement member. *See id.* at 3. In response to the non-regular waveform, the drive motor drives the fluid displacement member to displace fluid in the test chamber. *See id.* at 2-4.

23. By operating (*e.g.*, through its own testing) the DuraPulse, Defendant has performed accelerated testing of valved prosthetic devices. *See* Exhibit F at 1-4. When used, the DuraPulse generates an asymmetric waveform. *See id.* at 4. It has a drive motor and a connected fluid displacement member. *See id.* at 3. In response to the asymmetric wave form, the drive motor drives the fluid displacement member to increase and decrease pressure on fluid in the fluid chamber. *See id.* at 2-4. It controls the rate of change of differential pressures across the valve. *See id.* at 3; Exhibit E at 31.

24. Defendant's direct infringement has, and continues to be, willful and egregious. Defendant knew that it infringed the '538 Patent at least as of February 23, 2016, through a letter from BDC notifying Defendant of infringement. Independently, Defendant knew of the '538 Patent and that it reads on the DuraPulse because the '538 Patent was cited in the prosecution a patent application directed to the DuraPulse. Despite knowing of its infringement and that it had no reasonable defense, Defendant deliberately and in bad faith continued its infringing activities.

**SECOND CAUSE OF ACTION
INDIRECT INFRINGEMENT OF THE '538 PATENT**

25. BDC incorporates by reference each of the allegations in paragraphs 1-24 above.

26. Defendant has actively induced and contributed to, and continues to actively induce and contribute to, infringement of at least one claim of the '538 Patent by the end-users of its products without authorization from BDC.

27. For example, and without limitation, Defendant has actively induced and contributed to users of the DuraPulse performing every step of at least one claim of the '538 Patent.

28. At least as of February 23, 2016, Defendant knew of the '538 Patent and that end-users operating the DuraPulse would directly infringe at least independent claim 10 and dependent claims 11-13, either literally or under the doctrine of equivalents. Defendant specifically marketed the DuraPulse to users for performing accelerated testing of valved prosthetic devices. *See* Exhibit E at 9; *see generally* Exhibit F; <https://www.youtube.com/watch?v=KgmpQCRrYpQ&feature=youtu.be>). Defendant's marketing and other materials show users how to operate the DuraPulse in only an infringing manner. Upon information and belief, the DuraPulse can be used in only an infringing manner, as reflected in Defendant's marketing and other materials. Upon information and belief, Defendant has sold the DuraPulse, and by operating the DuraPulse, end users have performed accelerated testing of valved prosthetic devices. *See* Exhibit F at 1-4. When used, the DuraPulse generates an asymmetric waveform. *See*

id. at 4. It has a drive motor and a connected fluid displacement member. *See id.* at 3. In response to the asymmetric wave form, the drive motor drives the fluid displacement member to increase and decrease pressure on fluid in the fluid chamber. *See id.* at 2-4. It controls the rate of change of differential pressures across the valve. *See id.* at 3; Exhibit E at 31.

29. Defendant's active inducement and contributory infringement has been, and continues to be, willful and egregious. Defendant knew that using the DuraPulse would directly infringe the '538 Patent at least as of February 23, 2016, through a letter from BDC notifying Defendant of infringement. Independently, Defendant knew of the '538 Patent and that it reads on the operation of the DuraPulse because the '538 Patent was cited in the prosecution a patent application directed to the DuraPulse. Despite knowing that end-users' operation of the DuraPulse would directly infringe and that there was no reasonable defense to infringement, Defendant deliberately and in bad faith continued to actively induce and contribute to end-users' direct infringement.

THIRD CAUSE OF ACTION DIRECT INFRINGEMENT OF THE '708 PATENT

30. BDC incorporates by reference each of the allegations in paragraphs 1-29 above.

31. On January 14, 2014, the '708 Patent, entitled a "Fatigue Testing System for Prosthetic Devices," was duly and legally issued by the United States Patent and Trademark Office.

32. Each claim of the '708 Patent is valid and enforceable.

33. Since at least December 2015, Defendant has directly infringed at least one claim of the '708 Patent and, unless enjoined, will continue to do so, by making, using (*e.g.*, through its own testing), offering for sale, selling and/or importing into the United States infringing products without authorization from BDC.

34. For example, and without limitation, the DuraPulse meets every limitation of at least independent claim 17 and dependent claims 21-23 of the '708 Patent, either literally or under the doctrine of equivalents.

35. The DuraPulse is a device for performing accelerated testing of valved prosthetic devices in a pressurized environment. *See* Exhibit F at 2-3. It has a fluid distribution chamber and includes a manifold defining a port for holding a sample holder. *See* <https://www.youtube.com/watch?v=KgmpQCRrYpQ&feature=youtu.be> at 0:17-0:23, 0:43-0:48. An aperture on the bottom face of the fluid distribution chamber is in fluid communication with a pressure source. *See id.* A sample holder is placed in a port defined by the first manifold. *See id.* at 0:23-0:29. A fluid return chamber has a manifold that is disposed opposite the first manifold. *See id.* at 0:17-0:23, 0:43-0:48. The ports at the top and bottom of the sample holder connect the fluid distribution chamber and the fluid return chamber. *See id.* It has a compliance chamber where gas, which compresses under a pressure placed upon fluid in the test chamber, is held. *See id.*

36. Defendant's direct infringement has, and continues to be, willful and egregious. Defendant knew that it infringed the '708 Patent at least as of February 23, 2016, through a letter from BDC notifying Defendant of infringement. Independently, Defendant knew of the '708 Patent and that it reads on the DuraPulse because the '708

Patent was cited in the prosecution a patent application directed to the DuraPulse.

Despite knowing of its infringement and that it had no reasonable defense, Defendant deliberately and in bad faith continued its infringing activities.

**FOURTH CAUSE OF ACTION
DIRECT INFRINGEMENT OF THE '224 PATENT**

37. BDC incorporates by reference each of the allegations in paragraphs 1-36 above.

38. On November 17, 2015, the '224 Patent, entitled a "Fatigue Testing System for Prosthetic Devices," was duly and legally issued by the United States Patent and Trademark Office.

39. Each claim of the '224 Patent is valid and enforceable.

40. Since at least December 2015, Defendant has directly infringed at least one claim of the '224 Patent and, unless enjoined, will continue to do so, by using (*e.g.*, through its own testing) infringing products without authorization from BDC.

41. For example, and without limitation, by using the DuraPulse, Defendant practices every step of at least independent claim 1 and dependent claim 6 of the '224 Patent, either literally or under the doctrine of equivalents.

42. By operating (*e.g.*, through its own testing) the DuraPulse, Defendant has performed accelerated testing of valved prosthetic devices. *See* Exhibit F at 1-4. When used, the DuraPulse drives fluid within the device well above a normal physiological level, between 15 Hz (900 BPM) and over 30 Hz (1,800 BPM). *See id.* at 3. During the driving stroke, the DuraPulse stores working fluid in an excess volume area at the top of

the chamber. *See*

<https://www.youtube.com/watch?v=KgmpQCRrYpQ&feature=youtu.be> at 0:43-0:48. It then releases the stored volume of test system fluid during a return stroke that closes the valved prosthetic device. *See id.*

43. Defendant's direct infringement has and, continues to be, willful and egregious. Defendant knew of the '224 Patent and that it infringed the '224 Patent at least as of February 23, 2016, through a letter from BDC notifying Defendant of infringement. Despite knowing of its infringement and that it had no reasonable defense, Defendant deliberately and in bad faith continued its infringing activities.

FIFTH CAUSE OF ACTION ACTIVE INDUCEMENT OF THE '224 PATENT

44. BDC incorporates by reference each of the allegations in paragraphs 1-43 above.

45. Defendant has actively induced and contributed to, and continues to actively induce and contribute to, infringement of at least one claim of the '224 Patent by the end-users of its products without authorization from BDC.

46. For example, and without limitation, Defendant has actively induced and contributed to users of the DuraPulse performing every step of at least one claim of the '224 Patent.

47. At least as of February 23, 2016, Defendant knew of the '224 Patent and that end-users operating the DuraPulse would directly infringe at least independent claim 1 and dependent claim 6, either literally or under the doctrine of equivalents. Defendant

specifically marketed the DuraPulse to users for performing accelerated testing of valved prosthetic. *See* Exhibit E at 9; *see generally* Exhibit F;

<https://www.youtube.com/watch?v=KgmpQCRrYpQ&feature=youtu.be>). Defendant's marketing and other materials, which show users how to operate the DuraPulse, demonstrate that the DuraPulse can be used in only an infringing manner. Upon information and belief, the DuraPulse can be used in only an infringing manner, as reflected in Defendant's marketing and other materials. Upon information and belief, Defendant has sold the DuraPulse, and end users have performed accelerated testing of valved prosthetic devices. *See* Exhibit F at 1-4. When used, the frequency at which the DuraPulse operates is well above 200 BPM. *See id.* at 3. During the driving stroke, the DuraPulse stores working fluid in an excess volume area at the top of the chamber. *See* <https://www.youtube.com/watch?v=KgmpQCRrYpQ&feature=youtu.be> at 0:43-0:48. It then releases the stored volume of test system fluid during a return stroke that closes the valved prosthetic device. *See id.*

48. Defendant's active inducement and contributory infringement has been and, continues to be, willful and egregious. Defendant knew of the '224 Patent that using the DuraPulse would directly infringe the '224 Patent at least as of February 23, 2016, through a letter from BDC notifying Defendant of infringement. Despite knowing that end-user' operation of the DuraPulse would directly infringe and that there was no reasonable defense to infringement, Defendant deliberately and in bad faith continued to actively induce and contribute to end-users' direct infringement.

**SIXTH CAUSE OF ACTION
DIRECT INFRINGEMENT OF THE '935 PATENT**

49. BDC incorporates by reference each of the allegations in paragraphs 1-48 above.

50. On January 19, 2016, the '935 Patent, entitled a "Fatigue Testing System for Prosthetic Devices," was duly and legally issued by the United States Patent and Trademark Office.

51. Each claim of the '935 Patent is valid and enforceable.

52. Since January 19, 2016, Defendant has directly infringed at least one claim of the '935 Patent and, unless enjoined, will continue to do so, by making, using (*e.g.*, through its own testing), offering for sale, selling and/or importing into the United States infringing products without authorization from BDC.

53. For example, and without limitation, the DuraPulse meets every limitation of at least independent claim 1 and dependent claims 2, 3, 8, 9, and 12 of the '935 Patent, either literally or under the doctrine of equivalents.

54. The DuraPulse is a device for performing accelerated testing of valved prosthetic devices. *See* Exhibit F at 1-4. It has a pressure source to drive fluid within the device well above a normal physiological level, between 15 Hz (900 BPM) and over 30 Hz (1,800 BPM). *See id.* at 3. It has a pressurizable test chamber for containing the fluid. *See* <https://www.youtube.com/watch?v=KgmpQCRrYpQ&feature=youtu.be> at 0:43-0:48. On one side of the device, it has a fluid distribution chamber positioned, which is in fluid communication with the pressure source. *See id.* at 0:17-0:23, 0:43-

0:48. On another side, it has a fluid return chamber. *See id.* It has a fluid return conduit, which structurally and fluidly connects the fluid distribution chamber to the fluid return chamber. *See id.* It has an excess volume area, which is in fluid communication with the fluid return chamber and which can store fluid when under compression. *See id.*

55. Defendant's direct infringement has and, continues to be, willful and egregious. Defendant knew of the '935 Patent and that it infringed the '935 Patent at least as of February 23, 2016, through a letter from BDC notifying Defendant of infringement. Despite knowing of its infringement and that it had no reasonable defense, Defendant deliberately and in bad faith continued its infringing activities.

PRAYER FOR RELIEF

WHEREFORE, BDC prays for judgment as follows:

- A. A decree preliminarily and permanently enjoining Defendant, its officers, directors, employees, agents, and all persons in active concert with it, from infringing, and inducing others to infringe, each of the Patents-In-Suit;
- B. An award of BDC's damages caused by Defendant's infringement of each of the Patents-In-Suit;
- C. Enhancement of BDC's damages pursuant to 35 U.S.C. § 284;
- D. Costs of suit and attorneys' fees pursuant to 35 U.S.C. § 285;
- E. Pre-judgment interest; and
- F. Such other relief as justice requires.

JURY DEMAND

BDC demands a trial by jury on all issues so triable.

Dated: July 27, 2017

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